

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

OMNIA MEDICAL, LLC,

Plaintiff,

v.

Case No. 8:22-cv-145-VMC-TGW

PAINTEQ, LLC, et al,

Defendants.

_____ /

ORDER

This matter comes before the Court pursuant to the claim construction hearing held on January 30, 2023. For the reasons stated below, the claims are construed as set forth herein.

I. Background

Omnia “develops novel products that reduce operative time through safe and reproducible instrumentation, while achieving superior surgical outcomes.” (Doc. # 1-1 at ¶ 6). One such product is the PsiF™ System which is used for surgical procedures in sacroiliac joint (“SI Joint”) repair. (Id.). The PsiF™ System includes components designed to practice the method of at least one claim of the ‘511 Patent. (Id.).

PainTEQ manufactures, sells, and offers to sell products for use in surgical procedures for SI Joint repair and fusion,

including its LinQ™ SI Joint Stabilization System. (Doc. # 48 at 2).

There are two patents at issue in this action: U.S. Patent No. 11,083,511 "Method and Implant System for Sacroiliac Joint Fixation and Fusion" (the '511 Patent) and U.S. Design Patent No. D922,568 "Surgical Cannula" (the D568 Patent).

The '511 Patent is a utility patent that is directed to instruments and methods for fusing a SI Joint to repair the joint or to alleviate pain in the pelvis or spine. (Doc. # 63-2 at 2). The D568 Patent is a design patent that contains one claim for "the ornamental design for a surgical cannula, as shown and described," and includes ten figures showing the design from all views. (Doc. # 63-3 at 1). The patent holder, Orthocision, filed its application for the '511 Patent on December 18, 2019, and the patent was issued on August 10, 2021. (Doc. # 63-2). Orthocision filed its application for the D568 Patent on October 27, 2020, and the patent was issued on June 15, 2021. (Doc. # 63-3).

Omnia is the exclusive licensee of intellectual property owned by Orthocision, including the '511 Patent and the D568 Patent. (Doc. # 1-1 at ¶ 7). As the exclusive licensee, Omnia Medical has the right to use the licensed intellectual

property and to enforce, litigate, initiate court proceedings, and/or settle all past, present, and future claims arising from or related to the licensed intellectual property. (Id.).

PainTEQ and Omnia entered into a business relationship that began around December 2016. (Id. at ¶ 10). This relationship was solidified by a distribution and sales agreement (the "Stocking Agreement") between the companies. (Id. at ¶ 15). PainTEQ terminated the Stocking Agreement on or about February 19, 2019. (Id. at ¶ 32).

As relevant to Omnia's patent claims, the crux of Omnia's allegations is that PainTEQ's LinQ™ Products "are unlicensed and unauthorized copies or near copies of Omnia Medical's PsiF™ System tools." (Id. at ¶ 8). According to Omnia, after PainTEQ terminated the Stocking Agreement in February 2019, Omnia discovered in September 2019 that PainTEQ was selling equipment substantially similar to Omnia's, and distributing a Surgical Technique Guide that uses images of equipment identical to Omnia's. (Id. at ¶ 33).

Omnia alleges that PainTEQ has infringed and continues to infringe the '511 Patent by making, using, selling, offering to sell, and marketing its LinQ™ Products. (Id. at ¶ 112). Similarly, Omnia alleges that the surgical cannula

contained in the LinQ™ products infringes the D568 Patent. (Id. at ¶ 102-103).

On January 18, 2022, Omnia filed suit against PainTEQ and two of its agents, Sean LaNeve and Charles Girsch. (Doc. # 1-1). Omnia alleged infringement of the '511 and D568 Patents (Counts VI and VII) and also asserted twelve non-patent claims related to the Stocking Agreement. (Id.). On March 28 2022, PainTEQ, Mr. LaNeve, and Mr. Girsch filed a motion to dismiss the complaint. (Doc. # 18). The Court dismissed Counts I-V and VIII-XIV of Omnia's complaint for improper claim-splitting, based on the still-pending suit between the two parties in another action before this Court. (Doc. # 45).

PainTEQ answered the complaint on August 17, 2022, asserting four counterclaims, each for a declaratory judgment. (Doc. # 48). Counts I and II seek a declaratory judgment of invalidity and non-infringement, respectively, of the '511 Patent. (Id.). Counts III and IV seek a declaratory judgment of invalidity and non-infringement, respectively, of the '5568 Patent. (Id.).

Omnia filed its claim construction brief on November 4, 2022. (Doc. # 60). PainTEQ filed its opposition brief on November 21, 2022, (Doc. # 63), and Omnia replied on December

1, 2022. (Doc. # 65). The Court held a Markman hearing on January 30, 2023, where the parties presented evidence on the meaning of disputed language in the patents in suit. Following the hearing, and per the Court's request, Omnia filed a supplemental brief on February 2, 2023. (Doc. # 77). The Court now determines the meaning of this disputed language.

II. Legal Standard

"Patent infringement actions are composed of two phases." Alps S., LLC v. Ohio Willow Wood Co., No. 8:08-cv-1893-MSS-MAP, 2010 WL 2347046, at *1 (M.D. Fla. May 19, 2010) report and recommendation adopted, No. 8:08-cv-1893-MSS-MAP, 2010 WL 2293274 (M.D. Fla. June 7, 2010). "First, in the claim construction phase, the court determines the scope and meaning of the patent claims as a matter of law, and second, the claims are compared to the allegedly infringing device." Id. (citing Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998)).

The construction of claims is based primarily on intrinsic evidence: the claim language, the specification, and the prosecution history. Id. The claim language itself is first in importance when construing the meaning and scope of the patent. Id. Generally, the rule for claim interpretation is that:

[T]erms in the claim are to be given their ordinary and accustomed meaning. General descriptive terms will ordinarily be given their full meaning: modifiers will not be added to broad terms standing alone. In short, a court must presume that the terms in the claim mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of the claim terms. Thus, if the claim is unambiguous and clear on its face, the court need not consider the other intrinsic evidence in construing the claim.

Id. (quoting Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999)). The court must determine what the claim language would have meant to “a person of ordinary skill in the art in question at the time of the invention.” Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005). “The goal of claim construction is to give disputed terms their ‘ordinary and customary meaning’ as the term would mean to ‘a person of ordinary skill in the art in question . . . as of the effective filing date of the patent application.’” Targus Int’l LLC v. Grp. III Int’l, Inc., No. 20-21435-Civ-Scola, 2022 WL 18394869, at *2 (S.D. Fla. Jan. 5, 2022) (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

“When the meaning of words in a claim is in dispute, the specification and prosecution history can provide relevant information about the scope and meaning of the claim.” Electro

Med. Sys., S.A. v. Cooper Life Scis., Inc., 34 F.3d 1048, 1054 (Fed. Cir. 1994). This is because "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Phillips, 415 F.3d at 1313. "The specification contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make and use it." Vitronics Corp., 90 F.3d at 1582. The prosecution history "contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims." Id.

The specification "is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315 (citing Vitronics, 90 F.3d at 1582). "The [c]ourt must be careful, however, to avoid reading limitations from the specification into the claim." Ice House Am., LLC v. Innovative Packaging Techs., Inc., No. 3:05-cv-1294-VMC-TEM, 2008 WL 2856674, at *3 (M.D. Fla. July 22,

2008), clarified on denial of reconsideration, No. 3:05-cv-1294-VMC-TEM, 2008 WL 3305232 (M.D. Fla. Aug. 7, 2008).

"The claim is what limits the scope of the patent, not the specification." Id. Accordingly, "the [c]ourt [should] be equally careful to avoid reading the claims too broadly, as would be done if the [c]ourt read claim language according to its dictionary definition rather than in the context of the specification." Id.

Courts may also rely on claim differentiation to construe terms. "The doctrine of claim differentiation create[s] a presumption that each claim in a patent has a different scope." Versa Corp. v. Ag-Bag Intern. Ltd., 392 F.3d 1325, 1330 (Fed. Cir. 2004) (internal citation omitted). "The difference in meaning and scope between claims is presumed to be significant [t]o the extent that the absence of such difference in meaning and scope would make a claim superfluous." Id. (internal citation omitted). However, "the written description and prosecution history overcome any presumption arising from the doctrine of claim differentiation." Kraft Foods, Inc. v. Int'l Trading Co., 203 F.3d 1362, 1368 (Fed. Cir. 2000).

The court may also consider extrinsic evidence. Alps S., LLC, 2010 WL 2347046, at *3. Extrinsic evidence is evidence

that is external to the patent, such as expert testimony and dictionaries. Id. The purpose of this evidence is to:

provide background on the technology at issue, to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.

Phillips, 415 F.3d at 1318. While "the Court may also rely upon extrinsic evidence, such as treatises and dictionaries, to illuminate the meaning of claim terms, . . . it is considered less reliable, and thus, holds less weight in claim construction." Targus Int'l LLC, 2023 WL 110356, at *3 (citing Phillips, 415 F.3d at 1318).

III. Analysis

The claims at issue in this matter are six disputed terms recited in Claims 1, 2, 10, 14, 15, 18, and 19 of the '511 Patent, as well as the D568 Patent. The Court will address the '511 Patent first, before moving on to the D568 Patent.

A. The '511 Patent

The '511 Patent is a utility patent that is directed to instruments and methods for fusing the SI Joint to repair the joint or to alleviate pain in the pelvis or spine. (Doc. # 63-2 at 2). The Court will address in turn each disputed term

found in Claims 1, 2, 10, 14, 15, 18, and 19 of the '511 Patent.

1. "Driving Said Fusion Implant"

Claim Language	Omnia's Proposed Construction	PainTEQ's Proposed Construction	Court's Construction
Driving said fusion implant (Claim Nos. 10.e, 15, & 18.e)	Advancing the fusion implant	Applying a force via an impactor or torquing tool onto the fusion implant to advance the position thereof	Driving said fusion implant

Omnia contends that the phrase "driving said fusion implant" should be given its plain meaning, which does not include the use of an external tool. (Doc. # 60 at 10). PainTEQ's position is that because Claim 18 also includes a step for "advancing the inserter," the phrase "driving the fusion implant" must mean something other than "advancing the fusion implant." (Doc. # 63 at 7; Doc. # 63-2 at 44:54-59). PainTEQ also highlights the reference in the specification to a medical instrument kit, present in some embodiments, which may include "an impactor for driving the fusion implant into the joint[.]" (Doc. # 63-2 at 3:9-10, 3:56-57).

The Court agrees with Omnia that the phrase “driving said fusion implant” requires no construction and that PainTEQ’s proposed construction impermissibly limits the scope of the claim. While the specification may be a helpful guide in understanding the claim language, “it is important not to import into a claim limitations that are not part of the claim.” SuperGuide Corp. v. DirecTV Enterprises, Inc., 358 F.3d 870, 875 (Fed. Cir. 2004). In particular, “a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.” Id. Critically, the reference to the external tool in the specification is in the context of the medical equipment kit that the present invention relates to in some embodiments. (Doc. # 63-2 at 3:9-10). Adopting PainTEQ’s proposed language thus requires reading into a claim a particular embodiment “when the claim language is broader than the embodiment,” which is not permitted in claim construction. SuperGuide, 358 F.3d at 875. The Court thus finds that the phrase “driving the fusion implant” is plain on its face and needs no construction. See Pediatric Med. Devices, Inc. v. Indiana Mills & Mfg., Inc., No. 1:11-CV-2613-TCB, 2013 WL 2395994, at *13 (N.D. Ga. Apr. 26, 2013) (declining to provide a construction beyond a phrase’s plain

terms where the phrase “convey[ed] a meaningful limitation to a person of ordinary skill” in the art); see Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc., 249 F.3d 1341, 1349 (Fed. Cir. 2001) (holding district court did not err when it declined to construe a term when the meaning of that term did not depart from its ordinary meaning or otherwise require construction).!

2. “Protrusion”

Claim Language	Omnia’s Proposed Construction	PainTEQ’s Proposed Construction	Court’s Construction
Protrusion (in reference to the fusion implant) (Claim Nos. 1.d, 2, 10.d, 10.e, 15, 18.c, & 18.e)	Something that extends from a main body	A structure extending from the fusion implant configured to pierce or penetrate bone tissue	Something that extends from the fusion implant configured to pierce or penetrate bone tissue

Omnia contends that no construction is necessary for the term “protrusion” and that PainTEQ’s proposed construction improperly limits the term. (Doc. # 60 at 11). PainTEQ relies on the prosecution history to argue that said protrusions must be construed in a manner that excludes the type of ribbing featured on other implants. (Doc. # 63 at 10-11).

During prosecution of the '511 Patent, the USPTO found that the '511 Patent recited seven patentably distinct implants. (Doc. # 63-9 at 2-3). The examiner stated on the record that the implant depicted in figures 126-128, which is replicated below, has a "bullet-like body with no anchors/protrusions." (Id. at 2). The examiner instructed Orthocision to elect one of the seven distinct implants to pursue in the '511 Patent. (Id. at 3).

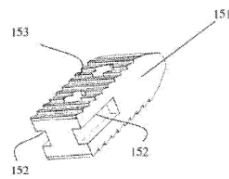


FIG. 126

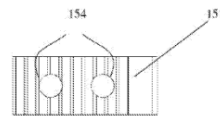


FIG. 127

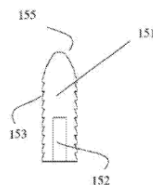


FIG. 128

(Doc. # 63-2 at 40). Orthocision was thus aware of the examiner's description of the implant depicted in figures 126-128 as lacking protrusions and continued to use the term in its claims. So, the term "protrusion" must be construed in

a manner that excludes the ribbing surface features on the implant depicted in figures 126-128.

The Court recognizes Omnia's argument that the above interaction between the USPTO and Orthocision involved an election of species, not an action on the merits of the claimed invention, and so does not involve a substantive examination of the claims or their claim terms. (Doc. # 65 at 5). However, for the purposes of claim construction, the USPTO's determination that the implant depicted in figures 126-128 lacks protrusions is nevertheless instructive. The Court is not limiting the scope of the claim based on a restriction requirement, or concluding that Orthocision disavowed the full scope of the term. Rather, the Court's construction of the term "protrusion" takes into account "how the PTO and the inventor understood the patent." Phillips, 415 F.3d at 1317. Because the USPTO's description of the implant depicted in figures 126-128 necessarily informs the scope of the term "protrusion," the Court must construe the term consistently.

With an eye to the prosecution history, the Court thus recognizes a distinction between an embodiment with external ribbing features and an embodiment with protrusions. The term "protrusions" necessarily excludes external ribbing features;

rather, it is limited to external features that pierce or penetrate.

3. "Engages with bone tissue"

Claim Language	Omnia's Proposed Construction	PainTEQ's Proposed Construction	Court's Construction
"Engages with bone tissue," "engagement of said at least one protrusion with said ilium and sacrum," "engagement with said bone tissue," and "engage with said articular surfaces" (Claim Nos. 1.d, 2, 10.d, 10.e, 18.e, & 19)	Creates a mechanical engagement between a protrusion and the bone	Interlocking with bone tissue in a piercing or penetrating manner in order to resist retractive forces	Configured for interlocking with bone tissue in the articular surface in a piercing or penetrating manner

Omnia contends the term "engage" as it appears in various claims should be given its plain meaning and that the doctrine of claim differentiation supports its proposed construction. (Doc. # 60 at 12-13). According to Omnia, the term "engagement" is broader than PainTEQ's proposed construction and encompasses more than fixation elements which interlock

with bone tissue or interlock in a piercing or penetrating manner. (Id. at 13). PaintEQ's position is that Orthocision acted as its own lexicographer to limit the meaning of "engagement with bone tissue in an articular surface" and disavowed alternative meanings during prosecution. (Doc. # 63 at 13).

"Disavowal requires that "the specification [or prosecution history] make[] clear that the invention does not include a particular feature[.]" Hill-Rom Servs., Inc. v. Stryker Corp., 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotations omitted). "[A] disclaimer/disavowal can occur from a simple statement differentiating the patent in question from prior art and that language of a specification or patent claim can, *by itself*, function as a disclaimer/disavowal." Zipshade Indus. (B.V.I.) Corp. v. Lowes Home Centers, LLC, No. 2:14-cv-05934-ODW (JC), 2017 WL 2766163, at *12 (C.D. Cal. June 26, 2017) (emphasis in original); see Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1304 (Fed. Cir. 1997) ("An argument contained in an [Information Disclosure Statement] which purports to distinguish an invention from the prior art thus may affect the scope of the patent ultimately granted.").

In an October 10, 2017, office action, the USPTO rejected three of Orthocision's claims in its application for the '757

Patent, which is the parent patent. (Doc. # 63-12 at 9); see Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed. Cir. 1999) (applying the prosecution history of one patent to a related, subsequently issued patent). All three of the rejected claims included the "engage with bone tissue" language. (Doc. # 63-11 at 6, 8). The USPTO explained that the Vestgaarden patent anticipated those claims. (Doc. # 63-12 at 9). In its response, Orthocision argued that Vestgaarden did not anticipate the claims at issue, distinguishing the Vestgaarden patent by noting that the Vestgaarden stabilizers "do not engage or penetrate the articular surfaces of the facet joint." (Doc. # 63-14 at 16). Instead, the Vestgaarden stabilizers "sandwich between the [bone] facets, not engaging the articular surfaces." (Id.). The prosecution history draws a distinction between an embodiment that "sandwiches" and an embodiment that "engages." Put differently, Orthocision's use of the term "engage" indicates that the term excludes stabilization elements that sandwich between bone facets. Based on the prosecution history of the '757 Patent, "engage" should not be construed as a broad term; rather, it is limited to piercing or penetrating.

4. "Preventing Pullout"

Claim Language	Omnia's Proposed Construction	PainTEQ's Proposed Construction	Court's Construction
Preventing pullout (Claim Nos. 1.d, 10.e, & 18.e)	Securing into position	Immobilizing (the fusion implant) against nondestructive removal via the application of a linear retraction force	Preventing pullout

Omnia contends that the phrase "preventing pullout" requires no construction. (Doc. # 60 at 14). PainTEQ argues that its proposed construction is necessary to clarify that the type of pullout at issue is nondestructive, rather than destructive, because the protrusions are incapable of preventing destructive pullout. (Doc. # 63 at 15-16). Further, PainTEQ contends the phrase "linear retraction force" is necessary to clarify that the type of pullout at issue is linear rather than rotational. (Id.).

The Court recognizes PainTEQ's argument that its construction serves to draw a distinction between destructive and nondestructive pullout. However, nothing in the specification or prosecution history indicates that such a

distinction is warranted. In short, there is no basis to construe the phrase “preventing pullout” as limited to nondestructive pullout. While PainTEQ contends that the protrusions cannot prevent destructive pullout, it similarly offers no support for that contention. In the face of PainTEQ’s conclusory statements, the Court declines to import such limitations into the claim.

As to the word “pullout,” PainTEQ offers the phrase “linear retraction force” to indicate that the operative force is linear, rather than rotational. (Doc. # 63 at 16). However, at the claim construction hearing, PainTEQ stated that the phrase “linear retraction force” is just another way of describing pullout. Because the word “pullout” by its plain terms indicates a linear force, the Court does not find it necessary to provide further construction.

5. “Controlling the Advancement”

Claim Language	Omnia’s Proposed Construction	PainTEQ’s Proposed Construction	Court’s Construction
Controlling the advancement (Claim Nos. 1.b & 14.b)	Guiding forward motion	Arresting the extent of axial progress (alternate construction) Controlling the depth of advancement	Controlling the depth of the advancement

Omnia contends that no construction is necessary for the phrase "controlling the advancement" and that PaintEQ's construction impermissibly narrows the scope of the phrase beyond its plain meaning. (Doc. # 60 at 15). PaintEQ's position is that the prosecution history indicates the phrase was meant to be understood as "controlling the depth of the advancement." (Doc. # 63 at 17-18).

During prosecution of the '511 Patent, Orthocision presented Claim 32 (which ultimately issued as Claim 1) which recited the limitation "controlling the advancement of surgical tools." (Doc. # 63-15 at 2). On July 17, 2020, the USPTO rejected Claim 32 as obvious, noting that the Stark patent disclosed a method for SI Joint repair where the working channel contained a hollow barrel for "controlling the advancement of surgical tools[.]" (Doc. # 63-16 at 4). In response, Orthocision submitted an amended application, narrowing the limitation in Claim 32 to "controlling the *depth to which* advancement of surgical tools passed through said working channel[.]" (Doc. # 63-17 at 2) (emphasis added).

On May 17, 2021, the USPTO examiner engaged in a telephone interview with Orthocision. (Doc. # 63-18 at 1). The examiner's summary of the interview noted that they

"[d]iscussed proposed amendments to overcome minor claim objections (grammatical and clarity issues). All amendments were agree[d] to." (Id.). Subsequently, on May 20, 2021, the USPTO issued a Notice of Allowance, which included an amendment to Claim 32. (Doc. # 63-19 at 9). The amendment replaced the phrase "controlling the depth to which advancement" with the phrase "controlling the advancement." (Id.).

The Court finds the prosecution history to be compelling evidence on the scope of the phrase "controlling the advancement" for two reasons. First, the Court finds that Orthocision acted as its own lexicographer when it advanced to the USPTO an interpretation of the phrase that included the limiting term "depth" in response to the obviousness rejection. See Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327, 1332 (Fed. Cir. 2004) (explaining that an inventor may act as its own lexicographer by offering a definition of specific terms in either the written description or the prosecution history). Orthocision's use of the term "depth" to distinguish the present invention from the Stark patent evinces its intent to limit the phrase "controlling the advancement" to "controlling the depth of the advancement."

Second, the USPTO's description of the amendments as grammatical, rather than substantive, demonstrates that the USPTO shared Orthocision's understanding of the phrase. Put differently, if removing the term "depth" was intended to broaden the claim, it would have transformed the change from a grammatical to a substantive amendment. Because the round of amendments that produced the final iteration of the claim did not purport to contain any substantive changes, the Court thus construes the claim to have the same substantive scope as Orthocision's proposed amendment. See (Doc. # 63-17 at 2).

During the claim construction hearing, the Court asked PainTEQ to expound on this issue. PainTEQ admitted that it was unable to conclude with certainty whether the omission of the term "depth" was a mistake by the USPTO or offer a concrete explanation for why the term was omitted. The Court similarly declines to speculate why the term was removed. Nevertheless, because the term "depth" was intended to distinguish the patent in suit from the prior art, and because no substantive edits occurred after Orthocision advanced such an interpretation to the USPTO, the Court construes the term accordingly.

6. "Fixes Relative Positions"

Claim Language	Omnia's Proposed Construction	PainTEQ's Proposed Construction	Court's Construction
Fixes relative positions (Claim Nos. 2, 10.e, & 19)	Secures positions of the bones	Mechanically holds the relative positions	Mechanically holds the relative positions

Omnia contends that no construction is necessary for the phrase "fixes relative positions" because it is clear on its face. (Doc. # 60 at 17). PainTEQ's position is that the phrase must be read in light of the specification, which acknowledges there are two ways to fix the relative positions of the sacrum and the ilium: mechanical holding and surgical fusion. (Doc. # 63-2 at 17-19). Thus, according to PainTEQ, its construction is necessary to clarify that the protrusions of the fusion implant recited in the '511 Patent do not cause bone fusion.

The Court agrees with PainTEQ that, read in light of the specification, the term "mechanically" is necessary to distinguish mechanical from biological fixation. See SuperGuide, 358 F.3d at 875 (noting that the explanations contained in the written description can facilitate understanding the claim language). In doing so, the Court

does not import a limitation into the specification from a particular embodiment; rather, the construction reflects that, in the broader context of the patent, which contains reference to multiple forms of fixation, the term “mechanically” clarifies the scope of the claims. Indeed, the patent specification discloses that bone fusion is promoted by bone-growth enhancing material within the fusion implant. (Doc. # 63-2 at 21:65-67). The Court’s construction thus reflects the fact that protrusions of the fusion implant do not cause bone fusion.

B. The D568 Patent

The D568 Patent is a design patent, not a utility patent. In claim construction for design patents, the Court need not “attempt to provide a detailed verbal description of the claimed design, as is typically done in the case of utility patents.” Egyptian Goddess, Inc. v. Swisa, Inc., 543 F.3d 665, 679 (Fed. Cir. 2008). This is largely because of the “recognized difficulties entailed in trying to describe a design in words[.]” Id. Therefore, the Federal Circuit has expressly affirmed minimal claim constructions that forego detailed verbal descriptions and rely primarily on the illustration included in the patent. See Unique Indus. Inc.

v. 965207 Alberta Ltd., 722 F. Supp. 2d 1, 8 (D.D.C. 2009) (collecting cases).

A design patent protects only the novel, ornamental features of the patented design. OddzOn Product, Inc. v. Just Toys, Inc., 122 F.3d 1396, 1405 (Fed. Cir. 1997). "Where a design contains both functional and non-functional elements, the scope of the claim must be construed in order to identify the non-functional aspects of the design as shown in the patent." Id.; see Richardson v. Stanley Works, Inc., 597 F.3d 1288, 1293 (Fed. Cir. 2010) (finding that the district court properly factored out the functional aspects of a design patent during claim construction).

However, the mere fact that certain elements of a design are functional does not preclude those elements from having protectable ornamentation. For example, in Ethicon v. Endo-Surgery, Inc. v. Covidien, Inc., 796 F.3d 1312, 1332 (Fed. Cir. 2015), the Federal Circuit found that although the patent holder's design patents did not protect the general design concept of the functional elements of the patent, those elements "nevertheless ha[d] some scope - the particular ornamental designs of those underlying elements." Id. at 1334. Thus, courts must be careful not to "perform[] [the] functionality analysis at too high a level of abstraction,

focusing on the general concepts [of the functional elements] rather than the ornamental designs adorning those elements.”

Id.

Further, the Federal Circuit has also explained that, as part of claim construction, it may be helpful for the district court to point out “various features of the claimed design as they relate to the accused design and the prior art.” Egyptian Goddess, 543 F.3d at 680; see Lanard Toys Ltd. v. Dolgencorp LLC, 958 F.3d 1337, 1342–43 (Fed. Cir. 2020) (holding the district court did not err in claim construction of a design patent where it “pointed out the ornamental and functional features of the design as well as the various features as they relate to the prior art”).

Omnia is the exclusive licensee of the D568 Patent, which recites one claim for “the ornamental design for a surgical cannula, as shown and described.” (Doc. # 63-3 at 1). The ten exemplary figures are reproduced below:

Fig. 1

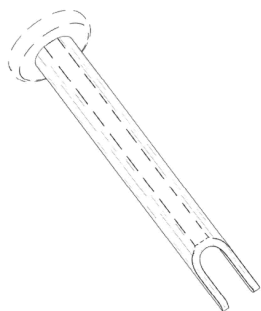


Fig. 2

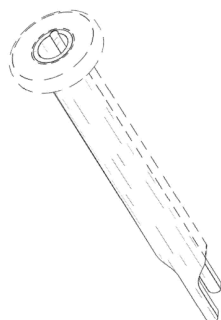


Fig. 3

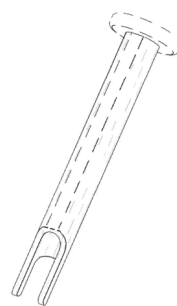


Fig. 4

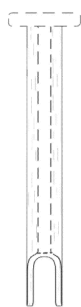


Fig. 5

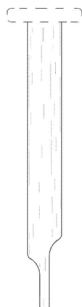


Fig. 6

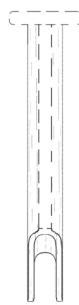


Fig. 7

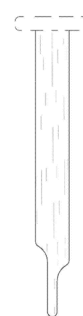


Fig. 8

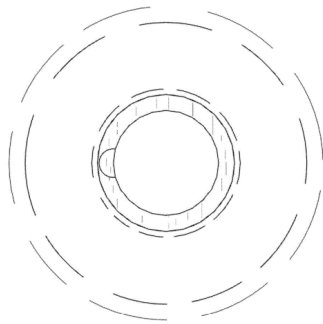


Fig. 9

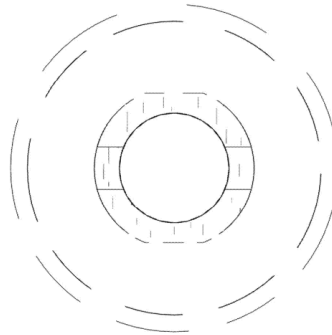
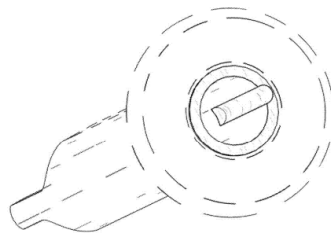


Fig. 10



(Doc. # 63-3) There are three issues pertaining to the claim construction of the D568 Patent: indefiniteness, disclaimer, and functionality. The Court will address each in turn.

1. Indefiniteness

As a threshold matter, PaintEQ contends that the D568 Patent is indefinite because it depicts the flat faces on the barrel of the cannula in both solid and broken lines. (Doc. # 63 at 20). According to PaintEQ, the D568 Patent is invalid for indefiniteness. (Id. at 23). Omnia's position is that the

D568 Patent is not indefinite because an ordinary observer would understand what is claimed and not claimed by viewing the design in the context of the application. (Doc. # 65 at 15). Further, during the claim construction hearing, Omnia posited that because indefiniteness is an invalidity argument, claim construction is not the proper juncture to address such an argument.

"Whether to decide the issue of invalidity based on indefiniteness at the claim construction stage depends on the particular circumstances and claims at issue in a given case, and is a matter within a court's discretion." Junker v. Med. Components, Inc., No. CV 13-4606, 2017 WL 4922291, at *2 (E.D. Pa. Oct. 31, 2017). While indefiniteness challenges are "linked to claim construction because a [c]ourt must attempt to determine what a claim means before it can determine whether the claim is invalid for indefiniteness," courts are not required to determine indefiniteness during claim construction proceedings. 3rd Eye Surveillance, LLC v. United States, 157 Fed. Cl. 673, 679 (Ct. Fed. Cl. 2022) (internal quotations omitted). And "district courts throughout the country have generally been reluctant to consider whether a patent is indefinite at the claim construction phase, rather than at the summary judgment phase." Junker, 2017 WL 4922291,

at *2; see, e.g., Indus. Tech. Research Inst. v. LG Elecs. Inc., No. 3:13-cv-2016-GPC-WVG, 2014 WL 6907449, at *2 (S.D. Cal. Dec. 8, 2014) (deferring “determination of indefiniteness to a later stage of the proceedings so the parties may thoroughly brief the Court on the matter”); CSB-Sys. Int’l Inc. v. SAP Am., Inc., No. CIV.A. 10-2156, 2011 WL 3240838, at *17 (E.D. Pa. July 28, 2011) (“Several well-settled principles [including the dispositive nature of an indefiniteness finding] . . . tend to discourage rulings on indefiniteness at the Markman stage.”); Takeda Pharm. Co. v. Handa Pharms., LLC, No. C-11-00840 JCS, 2012 WL 1243109, at *16 (N.D. Cal. Apr. 11, 2012) (“Due to the largely factual nature of [the indefiniteness] inquiry, the Court concludes that [the] question is more suitable for determination on summary judgment than at the claim construction phase of the case.”).

Here, the Court defers ruling on the indefiniteness issue until a later stage in the proceedings for two reasons. First, the claim at issue is not so abstract or meaningless as to render it indecipherable for claim construction purposes. See Cambria Co. LLC v. Hirsch Glass Corp., No. 21-10092 (MAS) (LHG), 2022 WL 4031422, at *5 (D.N.J. Sept. 2, 2022) (declining to find indefiniteness at the claim

construction stage where “the claims [were] not so abstract or meaningless to render them indecipherable”); Merck Sharp & Dohme Corp. v. Teva Pharms. USA, Inc., No. 17-6921 (MAS) (TJB), 2019 WL 943532, at *6 (D.N.J. Feb. 26, 2019) (deferring ruling on indefiniteness where the claims at issue were “sufficiently definite to survive claim construction” (internal quotations omitted)). The source of the alleged indefiniteness is the purported inconsistency between figures 1-4 and 6, and figures 5 and 7; specifically, that the former represents in broken lines the flat face along the barrel of the cannula, while the side view on the latter is represented with a solid line. As the Court will explain in more detail below, this purported inconsistency does not preclude one in the ordinary skill of the art from gleaned an overall sense of the design or from identifying the extent of the disclaimer. See Junker, 2017 WL 4922291, at *3 (explaining that the precedent holding that an inconsistency does not necessarily render a patent indefinite “cuts against a ruling on invalidity at the claim construction stage where, as here, the patent challenger’s argument for invalidity is based on alleged inconsistencies in the patent figures”).

Second, PainTEQ did not make a formal motion for an invalidity determination. See Id. at *1 (noting that

defendants did not formally move for an invalidity ruling and deferring ruling on indefiniteness until summary judgment); Pharmastem Therapeutics, Inc. v. Viacell, Inc., No. 02-148 GMS, 2003 WL 124149, at *1 (D. Del. Jan. 13, 2003) (declining to rule on indefiniteness at the claim construction phase and noting that the defendants had not “filed a motion seeking to invalidate the patents on indefiniteness grounds” but had rather “assert[ed] their arguments in their opposition claim construction brief”). The Court believes that the issue of indefiniteness would be best served by more complete and targeted briefing. See Takeda Pharm., 2012 WL 1243109, at *16 (explaining the “largely factual nature” of the indefiniteness inquiry counsels in favor of determining the issue on summary judgment); Indus. Tech. Research Inst., 2013 WL 6907449, at *3 (explaining that because the parties must present arguments on disputed claim terms at the claim construction hearing, they will not have “adequate time to fully address” the indefiniteness issue and deferring the indefiniteness determination to a later stage “so the parties may thoroughly brief the matter”). Thus, at this juncture in the proceedings, the Court will defer ruling on PainTEQ’s indefiniteness arguments.

2. Verbal versus Pictorial Construction

The second issue is whether a verbal construction of the patent features, as advanced by PaintEQ, is necessary. PaintEQ proposes a verbal construction for five different elements of the D568 Patent. (Doc. # 63 at 32-37). Omnia's position is that the patent is best represented by the figures itself and that a verbal construction is not necessary. (Doc. # 65 at 20-21).

In discussing whether verbal claim construction is warranted, the Federal Circuit has explained that "an illustration depicts a design better than it could be by any description and a description would probably not be intelligible without the illustration." Crocs, Inc. v. Int'l Trade Comm'n, 598 F.3d 1294, 1302-03 (Fed. Cir. 2010) (internal quotations omitted). Thus, "[a]s a rule the illustration in the drawing views is its own best description." Id. at 1302 (citing Manual of Patent Examining Procedure ("MPEP") § 1503.01 (8th ed. 2006)).

However, while recognizing that a district court's decision regarding the level of detail to be used in describing the claimed design is discretionary, the Federal Circuit has also posited that "a trial court can usefully guide the finder of fact by addressing a number of other

issues that bear on the scope of the claim.” Egyptian Goddess, 543 F.3d at 680. “Those include such matters as describing the role of particular conventions in design patent drafting, such as the role of broken lines . . . and distinguishing between those features of the claimed design that are ornamental and those that are purely functional[.]” Id.

Here, PaintEQ does not explain why a verbal construction is preferable to relying on the figures included in the patent specification. The Court, as a general matter, thus declines to depart from the typical approach of permitting the exemplary figures to represent the design. However, the Court also recognizes that the D568 Patent disclaims certain elements of the design. The Court will engage in verbal claim construction only to the extent necessary to clarify which elements are disclaimed, as well as to distinguish functional elements from those which are ornamental. Id.

To construe the single claim recited in the D568 Patent, the Court thus relies on the exemplary drawings above, except to the extent that a verbal construction is warranted to indicate disclaimer and to distinguish which features are functional.

3. Disclaimed Elements of the D568 Patent

The parties dispute whether three elements of the D568 Patent are disclaimed: the flat faces running along the barrel of the cannula; the apex of the sacral contours in the yoke of the tangs; and the iliac contours of the yoke. The Court will address each in turn.

Beginning with the flat faces on the barrel of the cannula, Omnia contends that the broken lines along the flat face of the cannula identify the flat face as an unclaimed element of the design. (Doc. # 77 at 7). PaintEQ's position, its indefiniteness argument notwithstanding, is that the flat faces are part of the claimed design because figures 5 and 7 depict the faces with a solid line. (Doc. # 63 at 32).

For design patents, "it is appropriate to disclaim certain design elements using broken lines, provided the application makes clear what has been claimed." In re Owens, 710 F.3d 1362, 1367 n.1 (Fed. Cir. 2013); see MPEP § 1503.02(III) ("Unclaimed subject matter may be shown in broken lines for the purpose of illustrating the environment in which the article embodying the design is used. Unclaimed subject matter must be described as forming no part of the claimed design or of a specified embodiment thereof.").

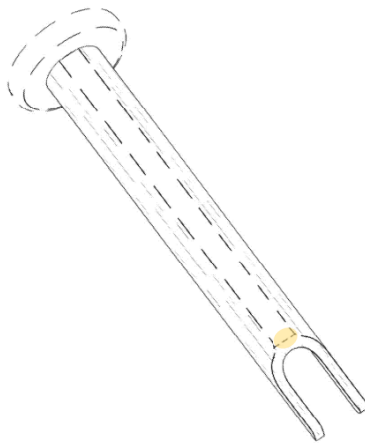
The Court agrees with Omnia that the flat faces on the barrel of the cannula are disclaimed. In figures 1-4 and 6, the flat faces are clearly depicted by broken lines. (Doc. # 63-3 at 4-9). While figures 5 and 7 depict the barrel of the cannula using only solid lines, these lines show the outer boundary of the cylindrical body, rather than the flat face. More specifically, the solid lines convey that Omnia claims the design of the barrel as a whole, rather than that it claims the flat face on the barrel. When viewed at an angle, like in figure 3, the broken lines clearly disclaim the flat face.

However, the Court recognizes that this perceived inconsistency forms the basis of PainTEQ's indefiniteness argument, which the Court has deferred ruling on until the summary judgment stage. While the Court finds that the purported inconsistency does not render the D568 Patent indefinite for the purposes of claim construction, PainTEQ is not prevented from raising invalidity arguments, including indefiniteness, at a later stage in these proceedings. See Junker, 2017 WL 4922291, at *3 (declining to rule on indefiniteness during the claim construction phase where the patent challenger's argument for indefiniteness was based on alleged inconsistencies in the patent figures).

Next, the parties dispute whether whether the apex of the sacral contours in the yoke of the tangs is disclaimed. According to PaintEQ, the depiction of the apex of the yoke in broken lines, as shown in figure 1, represents that the apex is disclaimed. (Doc. # 63 at 33). Omnia contends that the broken lines act as a disclaimer only as to the distal end of the flat face of the cannula, and that the surface which lies beneath the lines – the apex of the yoke – is claimed. (Doc. # 77 at 8).

More specifically, the issue here is that the broken lines at issue – which the Court has highlighted below in yellow – represent the point at which the disclaimed flat face of the barrel interfaces with the apex of the yoke, which Omnia contends is not disclaimed.

Fig. 1



"In general, when broken lines are used, they should not intrude upon or cross the showing of the claimed design and should not be of heavier weight than the lines used in depicting the claimed design." MPEP § 1503.02(III). In some circumstances, "[w]hen broken lines cross over the full line showing of the claimed design and are defined as showing environment, it is understood that the surface which lies beneath the broken lines is part of the claimed design." Id. However, "[w]here a broken line showing of environmental structure must necessarily cross or intrude upon the representation of the design and obscure a clear understanding of the design, such an illustration should be included as a separate figure, in addition to other figures which fully disclose the subject matter of the design." Id.

Here, although Omnia contends that the broken line depicted in figure 1 is defined as showing environment, the D568 Patent fails to include the broken line as a separate figure. Indeed, all three figures showing the sacral contour include only the broken line. Because Omnia's argument assumes that the broken line would "cross or intrude upon the representation of the design," the illustration with the broken line was required to have been included as a separate figure. No figure in the D568 Patent "fully disclose[s] the

subject matter of the design” as advanced by Omnia. Accordingly, in the absence of separate figures depicting what Omnia purports to be the full scope of the claimed design, the Court construes the dotted line across the yoke to disclaim both the distal edge of the flat face on the barrel and what lies beneath.

Finally, the parties dispute whether the lines between the flat face of the barrel and the iliac contour are broken lines representing disclaimer, or whether the lines claim an ornamental design of surface features. For clarity, the lines at issue are outlined in red below:

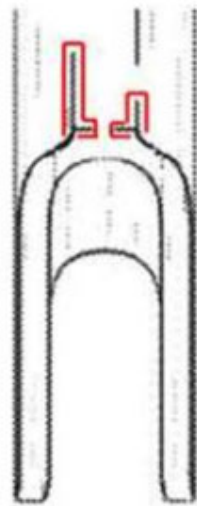


Fig. 6

Omnia contends that the lines at issue are broken lines intended to disclaim the flat face of the barrel of the

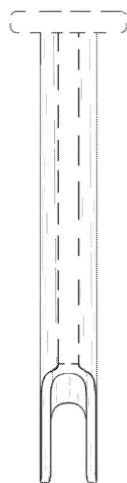
cannula. (Doc. # 77 at 10). PaintEQ argues that the lines depict a design feature on the yoke of the cannula where the iliac contour meets the flat face. (Doc. # 63 at 37). According to PaintEQ, Omnia's position that the design feature is a confluence of broken lines is inconsistent with figure 3, as shown below:

Fig. 3



The Court finds that the broken line between the flat face of the barrel and the iliac contour represent disclaimer, not a feature of the barrel. Viewed in the larger context of the exemplary figures, the broken lines running down the face of the barrel disclaim the flat face of the barrel. The longitudinal lines that intersect with the broken lines running latitudinally are a continuation of the broken lines on the flat face of the cannula, as shown more clearly in the full figure 6 below:

Fig. 6



The broken lines thus represent disclaimer, not surface features. That these lines happen to intersect some of the solid lines across the iliac contour of the cannula does not change their function. While PaintTEQ attempts to argue that the lines depicted in figure 6 are solid lines and thus treating them as a disclaimer would render figure 3 a "disclaimer statement directed to any portion of the claimed design that is shown in solid lines in the drawings," the Court is unpersuaded for two reasons. See MPEP § 1503.01.II.B(1). First, the Court finds that the lines in figure 6 where the flat face meets the iliac contour are broken, not solid. Any perception that the lines are solid is created by the intersection of the longitudinal and

latitudinal broken lines. Second, the perspective view shown in figure 3 clearly demonstrates that the lines are broken disclaimer lines, rather than solid lines. While the Court recognizes PaintTEQ's position that figure 3 is inconsistent with figure 6, such an argument is better addressed at the invalidity stage.

4. Ornamental versus Functional Features

The parties also dispute the extent to which certain features of the D568 Patent are ornamental as opposed to functional. Omnia contends that every element of the D568 Patent contributes to the overall ornamentation of the design and that it is improper to "filter out" functional features. (Doc. # 60 at 18). According to Omnia, because there are different possible designs for each element of the surgical cannula, each functional element also contains a degree of ornamentation. (Id. at 19). PaintTEQ argues that three features of the D568 Patent are essential to the use or purpose of the surgical cannula and thus should be distinguished as functional. (Doc. # 63 at 28-29). Those three elements are the barrel of the surgical cannula; the distal end; and the flat faces on the cannula. (Id. at 29-31).

For the purposes of claim construction, the Court is thus tasked with distinguishing the underlying functional

elements of the design, which are not protected, from the particular ornamental features of those elements, that are protected.

The Federal Circuit has set forth a list of factors for courts to consider in determining whether a design claim was dictated by function, including:

whether the protected design represents the best design; whether alternative designs would adversely affect the utility of the specified article; whether there are any concomitant utility patents; whether the advertising touts particular features of the design as having specific utility; and whether there are any elements in the design or an overall appearance clearly not dictated by function.

PHG Techs., LLC v. St. John Companies, Inc., 469 F.3d 1361, 1367 (Fed. Cir. 2006). While acknowledging that these factors were introduced to assist courts in assessing validity, the Federal Circuit has nevertheless explained that they “serve as a useful guide for claim construction functionality as well.” Sport Dimension, Inc. v. Coleman Co., 820 F.3d 1316, 1322 (Fed. Cir. 2016).

Further, “[w]hen there are several ways to achieve the function of an article of manufacture, the design of the article is more likely to serve a primarily ornamental purpose.” L.A. Gear, Inc. v. Thom McAn Shoe Co., 988 F.2d 1117, 1123 (Fed. Cir. 1993). Indeed, courts may take certain

functional elements into account during claim construction where the scope of the patent is "limit[ed] . . . to its overall ornamental visual impression[.]" OddzOn, 122 F.3d at 1405; see Sport Dimension, 820 F.3d at 1322 (rejecting the district court's claim construction when it eliminated functional features from the claim entirely and noting that functional features should not be filtered out when they "contribute to the overall ornamentation of the design"). And the Federal Circuit has cautioned against an approach that focuses on the "aggregation of separable elements" instead of "the overall ornamentation of a design." Sport Dimension, 820 F.3d at 1322.

Here, the Court concludes that the dimensions of the barrel of the cannula are ornamental features. The remainder of the features are functional and outside the scope of the patent. The Court will address each feature in turn.

Beginning with the barrel of the surgical cannula, Omnia's position is that the ornamental features are the proportions and slenderness ratio of the barrel of the cannula. (Doc. # 65 at 16-17). In contrast, PaintEQ contends that the proportions of the barrel are functional because they are dictated by its intended purpose; that is, the cannula must be "long enough to reach the surgical site from

above the patient, it must be wide enough to accommodate passage of the fusion implant and the instruments used in performing the surgery, and it must be narrow enough to accomplish 'minimally invasive surgery.'" (Doc. # 63 at 29).

The Court agrees with PaintEQ that the smooth outer surface and contours of the barrel, and the guidance slot within the barrel, are dictated by their functionality. Because the cannula is inserted and extracted from the surgical site, the smooth outer surface and contours are essential to the design. See Ethicon Endo-Surgery, 796 F.3d at 1328 (explaining that a feature is functional where it is essential to the use of an article). Likewise, the '511 Patent – a utility patent – claims the guidance slot as a functional feature; specifically, as a stopping mechanism. (Doc. # 63-2 at 42:1-3); see PHG Techs., 469 F.3d at 1367 (noting that the existence of utility patents can inform a court's functionality analysis). These features of the cannula are thus essential to its function.

However, while the Court finds that the general shape of the barrel is dictated by functionality, PaintEQ does not provide any support for the proposition that the precise proportions of the cannula are purely functional. See Sport Dimension, 820 F.3d at 1322 (explaining that features with a

functional purpose can nevertheless be considered ornamental). The Court thus concludes that the specific dimensions of the cannula are an ornamental feature.

Next, as to the tangs, or arms, at the distal end of the surgical cannula, Omnia's position is that the ornamental feature is the shape of the distal end of the cannula, and placement and shape of the tangs. (Doc. # 63 at 17). PainTEQ, on the other hand, contends that the bluntness and the contours of the tangs are essential to its function. The Court agrees with PainTEQ that the tangs are dictated by their functionality. In its application to the USPTO for the '129 Patent, Orthocision explicitly stated that the bluntness of the tangs is integral to their function; that is, to prevent the tangs from penetrating the bone. (Doc. # 63-24 at 18). Likewise, the shape and size of the tangs are also integral to their function. The '129 Patent explains that the "instrumentation described herein will work with a patient of any size because the arms set the width of the SI joint to a uniform distance regardless of the size or scale of the sacrum or ilium." (Doc. # 63-25 at 9:41-44). In other words, the shape and size of the tangs are specifically designed to ensure that the cannula is compatible with all patients. This

feature is thus dictated by function, rather than ornamentation.


Finally, as to the flat faces which run along the barrel of the cannula, Omnia contends that the functions advanced by PainTEQ can be achieved by "various other designs." (Doc. # 65 at 18). PainTEQ contends that the flat faces are functional features. (Doc # 63 at 31). The Court need not decide this issue because the flat faces are disclaimed. See OddzOn, 122 F.3d at 1405 (explaining that a design patent only protects the novel, ornamental features of a patented design); In re Owens, 710 F.3d at 1367 n.1 (noting that the use of broken lines indicates that an element of the design drawings is not claimed by the design patent). Regardless of functionality, the disclaimer eliminates protection for the flat faces in the D568 Patent.

Accordingly, it is

ORDERED, ADJUDGED, and DECREED:

The claim language in dispute in this case shall be construed as set forth in this Order.

DONE and **ORDERED** in Chambers in Tampa, Florida,
this 30th day of June, 2023.



VIRGINIA M. HERNANDEZ COVINGTON
UNITED STATES DISTRICT JUDGE